

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

INVERNESS MEDICAL INNOVATIONS, INC.,
INVERNESS MEDICAL SWITZERLAND GMBH, and
SPD SWISS PRECISION DIAGNOSTICS GMBH.

Plaintiffs-Counterclaim Defendants,

v.

CHURCH & DWIGHT CO., INC.,

Defendant-Counterclaim Plaintiff.

1:10-cv-10027-DPW

JURY TRIAL DEMANDED

ANSWER AND COUNTERCLAIM

Defendant-Counterclaim Plaintiff Church & Dwight Co., Inc. (“Church & Dwight”), by and through its undersigned counsel, hereby sets forth its Answer And Counterclaim to the Complaint For Patent Infringement of Plaintiffs Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and SPD Swiss Precision Diagnostics GmbH (collectively “Plaintiffs”) as follows:

PARTIES

1. Upon information and belief, Church & Dwight admits that Inverness Medical Innovations, Inc. (“Inverness”) is a Delaware corporation with its principal place of business at 51 Sawyer Road, Suite 200, Waltham, MA 02453, U.S.A.

2. Upon information and belief, Church & Dwight admits that Inverness Medical Switzerland GmbH (“Inverness Switzerland”) is a corporation organized and existing under the laws of Switzerland with its principal place of business in Zug, Switzerland.

3. Upon information and belief Church & Dwight admits that SPD Swiss Precision Diagnostics GmbH (“SPD”) is a corporation organized and existing under the laws of Switzerland with its principal place of business in Geneva, Switzerland.

4. Church & Dwight admits that it is a Delaware corporation with its principal place of business in Princeton, New Jersey.

JURISDICTION AND VENUE

5. Church & Dwight admits that, in commencing this action, Plaintiffs have made allegations that invoke the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, but denies that such allegations are true.

6. Church & Dwight admits that, in commencing this action, Plaintiffs have made allegations that invoke the jurisdiction of this Court under 28 U.S.C. §§ 1331 and 1338(a), but denies that such allegations are true.

7. Church & Dwight admits that, in commencing this action, Plaintiffs have made allegations that invoke venue in this Court pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b), but denies that such allegations are true and denies that this district is the most convenient forum for this action.

COUNT ONE

INFRINGEMENT OF U.S. PATENT NO. 7,317,532

8. In response to Paragraph 8 of the Complaint, Church & Dwight repeats and realleges its responses above to Paragraphs 1 through 7 of the Complaint as if set forth fully herein.

9. Church & Dwight admits that Exhibit A to the Complaint, the document identified by Plaintiffs as U.S. Patent No. 7,317,532 (“the ‘532 patent”), is entitled “Flow Sensing for Determination of Assay Results” and that it states that it was issued on January 8,

2008. Church & Dwight denies that the '532 patent was duly issued, and is valid and enforceable. Church & Dwight is without knowledge or information sufficient to form a belief as to the truth of the remaining averments in Paragraph 9 of the Complaint, and therefore denies them.

10. Church & Dwight is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 10 of the Complaint, and therefore denies them.

11. Upon information and belief, Church & Dwight admits that SPD and Inverness market and sell nationwide home pregnancy tests under the brand name CLEARBLUE®Easy™. Church & Dwight is without knowledge or information sufficient to form a belief as to the truth of the remaining averments in Paragraph 11 of the Complaint, and therefore denies them.

12. Church & Dwight is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 12 of the Complaint, and therefore denies them.

13. Church & Dwight admits that it markets and sells nationwide digital pregnancy tests under the brand name FIRST RESPONSE® GOLD EARLY RESULT and that the FIRST RESPONSE® GOLD EARLY RESULT digital pregnancy test competes with, *inter alia*, the CLEARBLUE®Easy™ digital pregnancy test. Church & Dwight denies the remaining allegations of Paragraph 13 of the Complaint.

14. Church & Dwight denies the allegations contained in Paragraph 14 of the Complaint.

15. Church & Dwight denies the allegations contained in Paragraph 15 of the Complaint.

16. Church & Dwight denies the allegations contained in Paragraph 16 of the Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

17. Plaintiffs have failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

18. Church & Dwight has not infringed, willfully infringed, contributorily infringed, or induced infringement of any valid and enforceable claim of the '532 patent, either literally or under the doctrine of equivalents, and is not liable for any acts of willful infringement of the '532 patent. Furthermore, the claims of the '532 patent are limited by the text of the patents, the prosecution history, and/or the prior art so that Plaintiffs are estopped, or otherwise precluded, from asserting that any claim is infringed by Church & Dwight, literally or by equivalents.

THIRD AFFIRMATIVE DEFENSE

19. Upon information and belief, the claims of the '532 patent are invalid, void, and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, and 256.

FOURTH AFFIRMATIVE DEFENSE

20. Plaintiffs' claims are barred by the doctrine of laches, acquiescence and/or waiver because Plaintiffs have unreasonably delayed in bringing this action to the detrimental prejudice of Church & Dwight. As set forth below in Paragraphs 9 through 19 of Church & Dwight's Counterclaims, which are incorporated as though fully set forth herein, Plaintiffs' delay includes waiting to bring this action until after Inverness settled charges brought by the Federal Trade Commission ("FTC") that Inverness acted illegally to stifle competition in the U.S. market for consumer pregnancy tests, and that it acted illegally to maintain its monopoly with respect to

such products. Among other things, the FTC's charges related to illegal conduct directed against Church & Dwight. In addition, Plaintiffs' delay also includes waiting to bring this action until after Church & Dwight obtained rights to other patents licensed by Inverness – *i.e.*, the Metrika patents.

FIFTH AFFIRMATIVE DEFENSE

21. Plaintiffs' claims are barred by the doctrine of estoppel, acquiescence and/or waiver because Plaintiffs, through misleading conduct and/or inaction, led Church & Dwight to reasonably infer that Plaintiffs did not intend to enforce the '532 patent against Church & Dwight, Church & Dwight relied on that conduct, and Church & Dwight will be materially prejudiced if Plaintiffs are allowed to proceed with their claims. As set forth below in Paragraphs 9 through 19 of Church & Dwight's Counterclaims, which are incorporated as though fully set forth herein, Plaintiffs' misleading conduct and/or inaction includes waiting to bring this action until after Inverness settled charges brought by the FTC that Inverness acted illegally to stifle competition in the U.S. market for consumer pregnancy tests, and that it acted illegally to maintain its monopoly with respect to such products. Among other things, the FTC's charges related to illegal conduct directed against Church & Dwight. In addition, Plaintiffs' misleading conduct and/or inaction also includes waiting to bring this action until after Church & Dwight obtained rights to other patents licensed by Inverness – *i.e.*, the Metrika patents.

SIXTH AFFIRMATIVE DEFENSE

22. The '532 patent is unenforceable by reason of Plaintiffs' unclean hands and/or patent misuse in attempting to enforce the '532 patent in bad faith, knowing that the '532 patent is invalid, unenforceable, and/or not infringed by Church & Dwight in order to restrict or eliminate competition in the field of consumer pregnancy tests, contrary to the laws of the United

States. The '532 patent also is unenforceable by reason of Plaintiffs' conduct set forth in Paragraphs 9 through 19 of Church & Dwight's Counterclaims, which are incorporated as though fully set forth herein.

SEVENTH AFFIRMATIVE DEFENSE

23. Plaintiffs' claims and requests for relief are barred, in whole or in part, as a result of Plaintiffs' failure to comply with the marking and notice provisions of 35 U.S.C. § 287.

COUNTERCLAIMS

1. Counterclaim-Plaintiff Church & Dwight is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Princeton, New Jersey.

2. Upon information and belief, Inverness Medical Innovations, Inc. ("Inverness") is a Delaware corporation with its principal place of business at 51 Sawyer Road, Suite 200, Waltham, MA 02453, U.S.A.

3. Upon information and belief, Inverness Switzerland GmbH ("Inverness Switzerland") is a corporation organized and existing under the laws of Switzerland with its principal place of business in Zug, Switzerland.

4. Upon information and belief, SPD Swiss Precision Diagnostics GmbH ("SPD") is a corporation organized and existing under the laws of Switzerland with its principal place of business in Geneva, Switzerland.

5. These counterclaims seek declaratory judgment relief arising under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), and 1367.

7. This Court has personal jurisdiction over Plaintiffs.

8. Venue in this District over these counterclaims is proper under 28 U.S.C. §§ 1391 (b) and (c) and 1400(b).

FACTUAL ALLEGATIONS

9. Church & Dwight is in the business of researching, developing, marketing, and distributing consumer products, including consumer pregnancy tests sold under the brands First Response® and Answer®. Church & Dwight's First Response and Answer tests are in vitro diagnostic devices intended for the early detection of pregnancy hormones by lay consumers.

10. Upon information and belief, SPD is a joint venture between two large companies, Inverness and the consumer products giant The Procter & Gamble Company. Upon information and belief, SPD, together with its principal, Inverness, control approximately 70% of the consumer pregnancy test market in the United States.

11. Church & Dwight is SPD's and Inverness' main competitor in the consumer pregnancy test market. As described in greater below, SPD and Inverness have engaged in a pattern of wrongful conduct directed towards Church & Dwight for the purpose of inhibiting and impairing its ability to compete in the consumer pregnancy test market and otherwise causing it injury.

THE FTC CHARGES INVERNESS WITH ILLEGALLY ACTING TO STIFLE COMPETITION WITH CHURCH & DWIGHT

12. In a press release dated December 23, 2008, the United States Federal Trade Commission ("FTC") announced that it had charged Inverness with acting illegally to stifle future competition in the U.S. market for consumer pregnancy tests, and of acting illegally to maintain its monopoly with respect to such products. Among other things, the FTC's charges related to illegal conduct directed against Church & Dwight.

13. The FTC press release also announced that instead of defending against the FTC's charges, Inverness had entered into an Agreement Containing Consent Order ("Consent Agreement") to settle those charges. The Consent Agreement was designed, *inter alia*, to limit Inverness' ability to interfere with the future development and supply of competitive digital consumer pregnancy tests. To that end, the Consent Agreement included numerous provisions designed to protect Church & Dwight from Inverness' monopolistic activities.

14. The Consent Agreement was subject to a thirty-day public comment period, which expired on January 20, 2009. Upon information and belief, immediately thereafter, SPD embarked on a campaign of wrongful and illegal conduct, which was intended to injure, and has had the effect of injuring Church & Dwight's ability to compete in the consumer pregnancy test market.

15. On January 22, 2009, just two days after the thirty-day period for public comment on Inverness' settlement with the FTC ended, SPD sued Church & Dwight for alleged false advertising in connection with its marketing of consumer pregnancy tests. Despite the fact that Inverness (SPD's 50% owner) had just agreed to a Consent Agreement with the FTC that was expressly intended to promote competition with Church & Dwight, SPD also moved for a preliminary injunction, claiming an "urgent" need for Church & Dwight to be ordered to remove its digital consumer pregnancy tests from store shelves, thereby effectively putting Church & Dwight out of the digital consumer pregnancy test business. SPD demanded such relief even though Church & Dwight's allegedly false advertising and packaging statements had been circulating publicly for nearly a year. Upon information and belief, SPD waited to commence its suit until immediately after Inverness finalized its settlement with the FTC because it realized that doing so earlier might jeopardize that settlement.

16. SPD's false advertising action and its motion for a preliminary injunction against Church & Dwight remain pending in the United States District Court for the District of New Jersey.

17. One of the protections afforded Church & Dwight under the FTC Consent Agreement, and in a subsequently-issued FTC Decision and Order that incorporated the final terms of the FTC's settlement with Inverness, was the requirement that Inverness amend an exclusive patent license with Bayer Healthcare LLC ("Bayer") concerning certain patents relating to digital pregnancy tests (the "Metrika Patents"). The amendment was designed to permit Church & Dwight the opportunity to license the Metrika Patents from Bayer, which would not have otherwise been possible under Inverness' exclusive license arrangement.

18. After the FTC Consent Agreement became final, Bayer and Church & Dwight began negotiating a license under the Metrika Patents, and a license agreement between them was entered into in late 2009. Upon information and belief, SPD and Inverness were aware of those negotiations and that a license agreement for the Metrika Patents was executed at the end of last year.

19. Just days after Church & Dwight entered into the license agreement with Bayer for the Metrika Patents, SPD and Inverness sued Church & Dwight on U.S. Patent No. 7,317,532 ("the '532 patent") – a patent which issued two years earlier – suddenly claiming that it is infringed by Church & Dwight's digital consumer pregnancy tests. The complaint by SPD and Inverness seeks to bar Church & Dwight from manufacturing and selling those products, which would provide SPD and Inverness with a virtual monopoly in the digital consumer pregnancy test market. In short, even though the FTC Consent Agreement required Inverness to "stand aside" and allow Church & Dwight the opportunity to take a license for one set of patents

relating to digital pregnancy tests, as soon as that license was acquired, SPD and Inverness launched another attack on Church & Dwight's ability to market such products by claiming that they infringe another patent.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '532 PATENT

20. Church & Dwight repeats and realleges the allegations made in Paragraphs 1 through 19 of its Counterclaims as if set forth fully herein.

21. There is an actual, substantial, and continuing justiciable controversy between Church & Dwight and Plaintiffs regarding the infringement, validity, and enforceability of the '532 patent.

22. Church & Dwight has not directly infringed, contributorily infringed, or induced the infringement of any valid and enforceable claim of the '532 patent, either literally or under the doctrine of equivalents.

23. Church & Dwight has not willfully infringed any valid and enforceable claim of the '532 patent, either literally or under the doctrine of equivalents.

24. Church & Dwight is entitled to a declaration that it does not infringe any valid and enforceable claim of the '532 patent.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY
AND/OR UNENFORCEABILITY OF THE '532 PATENT

25. Church & Dwight repeats and realleges the allegations made in Paragraphs 1 through 24 of its Counterclaims as if set forth fully herein.

26. There is an actual, substantial, and continuing justiciable controversy between Church & Dwight and Plaintiffs regarding the validity and enforceability of the '532 patent.

27. The claims of the '532 patent are invalid, void, and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256, and 287.

28. The '532 patent is also unenforceable by reason of Plaintiffs' unclean hands and/or patent misuse in attempting to enforce the '532 patent in bad faith, knowing that the '532 patent is invalid, unenforceable, and/or not infringed by Church & Dwight in order to restrict or eliminate competition in the field of consumer pregnancy tests, contrary to the laws of the United States. Furthermore, the '532 patent is unenforceable because of Plaintiffs' unclean hands and/or patent misuse as set forth above at Paragraphs 9 through 19 of the Counterclaims.

29. Church & Dwight is entitled to a declaration that all claims of the '532 patent are invalid, void, and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Church & Dwight requests the entry of judgment in its favor on both Plaintiffs' Complaint and Church & Dwight's Counterclaims and prays that the Court:

(a) declare that Church & Dwight has not directly infringed, contributorily infringed, or induced the infringement of any claim of the '532 patent, either literally or under the doctrine of equivalents;

(b) declare that Church & Dwight has not willfully infringed, contributorily infringed, or induced the infringement of any claim of the '532 patent, either literally or under the doctrine of equivalents;

(c) declare that the '532 patent is invalid, void, and/or unenforceable;

(d) enjoin and restrain Plaintiffs, and those persons in active concert or participation with Plaintiffs, from further charges of infringement or acts of enforcement based upon the '532 patent against Church & Dwight, its actual and prospective customers, suppliers, and anyone else in privity with Church & Dwight;

(e) dismiss Plaintiffs' Complaint in its entirety with prejudice;

(f) declare that Plaintiffs take nothing by reason of its claims against Church & Dwight;

(g) conclude that this case is exceptional and award Church & Dwight its reasonable attorneys' fees under 35 U.S.C. § 285, together with the costs and disbursements of this action; and

(h) award such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Church & Dwight demands a jury trial on all claims, counterclaims, defenses, and other issues triable by a jury.

Respectfully submitted,

/s/ Jeremy P. Ocze
Jeremy P. Ocze (BBO #647509)
PROSKAUER ROSE LLP
One International Place
Boston, MA 02110
Tel: 617.526.9600
Fax: 617.526.9899
Email: joczek@proskauer.com

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Richard M. Goldstein*
James H. Shalek*
Baldassare Vinti*
John C. Stellabotte*
PROSKAUER ROSE LLP

1585 Broadway
New York, New York 10036-8299
Tel. 212.969.3000
* admitted *pro hac vice*

*Attorneys for Defendant-Counterclaim
Plaintiff Church & Dwight Co., Inc.*

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